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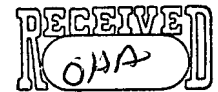
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February 16, 1994



VIA FACSIMILE AND FIRST CLASS MAIL

FEB 22 1994

Mr. Brian J. Malkin
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
FOOD AND DRUG ADMINISTRATION
5600 Fisher's Lane, Room 15-22
Rockville, Maryland 20857

**Re: Reality Female Condom
Patent Term Extension
U.S. Patent No. 4,735,621
FDA Docket No. 93E-0290**

Dear Mr. Malkin:

Chartex International Plc provides the following information in response to your inquiry regarding the early U.K. studies of the Reality/Femidom brand female condom.

The original U.K. clinical studies occurred at the following times.

Acceptability Study -	Started	October 1987
	Finished	May 1988
Efficacy Study -	Started	February 1989
	Finished	June 1990

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Neither an IDE nor IRB approval was required for these studies. The date on which the device was first used with human subjects as part of a clinical investigation to be filed with the FDA to secure pre-market approval of the device was in October, 1987. Therefore, the applicant identifies October 31, 1987, as the most certain date upon which such a study occurred.

If additional information is required, please do not hesitate to contact us.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Paul Grandinetti".

Paul Grandinetti

PG:jt

cc: Ms. Joan Hann